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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,408	12/26/2001	Larry Caldwell	CALD-005	3760

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/26/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/029,408

Applicant(s)

CALDWELL ET AL.

Examiner

Simon J. Oh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment and response, both received on 29 September 2003.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is precisely meant by the phrase "at least ameliorating a symptom associated with", as stated in independent Claims 1 and 24. By extension, as Claims 2-5, 19-23, and 25-27 ultimately depend on either Claim 1 or Claim 24, they are also considered to be indefinite.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Crandall and Biedermann *et al.* is hereby withdrawn.

Claims 1-18 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Biedermann *et al.*

The Petrus patent teaches compositions for the treatment of musculoskeletal disorders, which includes carpal tunnel syndrome (See Abstract; and Column 1, Lines 26-44). Among the suitable active ingredients disclosed are non-steroidal anti-inflammatory agents, such as indomethacin, diclofenac, ibuprofen and ketoprofen (See Column 4, Table 1). The disclosed compositions may be formulated into various dosage forms, including creams and films (See Column 3, Lines 18-25). Such compositions are suitable for treating humans afflicted with musculoskeletal disorders (See Column 13, Examples 3 and 4).

The Petrus patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel.

The Biedermann *et al.* patent is used here merely as a teaching reference to point out that diclofenac and indomethacin are known in the art as acetic acid derivatives (See Column 11, Line 66 to Column 12, Line 3).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. It is the position of the examiner that the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. The examiner finds no novelty in such claim limitations and shifts the burden onto the applicant to demonstrate how the instantly claimed invention shows unexpected results from what is known in the prior art. It is

Art Unit: 1615

the position of the examiner that topical forms disclosed in the prior art such as films sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art. Regarding Claims 24-28, the examiner does not see a patentable distinction between applying a cream or film to a patient's wrist to treat carpal tunnel syndrome and the method of treatment using a wristband comprising a patch as claimed. The examiner shifts the burden onto the applicant to demonstrate the particular inventive criticality of this feature.

Claims 1-18, and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards (U.S. Patent No. 5,989,559) and Biedermann *et al.*

The Petrus patent teaches compositions for the treatment of musculoskeletal disorders, which includes carpal tunnel syndrome (See Abstract; and Column 1, Lines 26-44). Among the suitable active ingredients disclosed are non-steroidal anti-inflammatory agents, such as indomethacin, diclofenac, ibuprofen and ketoprofen (See Column 4, Table 1). The disclosed compositions may be formulated into various dosage forms, including creams and films (See Column 3, Lines 18-25). Such compositions are suitable for treating humans afflicted with musculoskeletal disorders (See Column 13, Examples 3 and 4).

The Petrus patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Biedermann *et al.* patent is used here merely as a teaching reference to point out that diclofenac and indomethacin are known in the art as acetic acid derivatives (See Column 11, Line 66 to Column 12, Line 3).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. The examiner finds no novelty in such claim limitations and shifts the burden onto the applicant to demonstrate how the instantly claimed invention shows unexpected results from what is known in the prior art. It is the position of the examiner that topical forms disclosed in the prior art such as films sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art. Regarding Claims 24-28, the examiner does not see a patentable distinction between applying a cream or film to a patient's wrist to treat carpal tunnel syndrome and the method of treatment using a wristband comprising a patch as claimed. The examiner shifts the burden onto the applicant to demonstrate the particular inventive criticality of this feature.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Biedermann *et al.* and Shudo *et al.*

The relevant portions of Petrus and Biedermann *et al.* are detailed in the above rejection of Claims 1-18 and 24-28 under 35 U.S.C. 103(a).

Petrus and Biedermann *et al.* do not provide for kits containing a topical formulation and instructions for use according to a claimed method of treatment.

The Shudo *et al.* publication discloses kits comprising topical patch formulations as well as instructions for use, which may be printed or embodied in the form of electronic media (See Section [0044]). This publication is relied upon primarily as a teaching reference to show that it is known in the art that in certain instances, it may be desirable to provide kits that provide a topical formulation as well as instructions for use in accordance with a disclosed method of treatment.

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. In addition to the arguments presented in the above rejections, the provision of topical dosage forms in a kit that further comprises instructions for use in accordance with the instantly claimed methods of treatment of carpal tunnel syndrome is also considered by the examiner to be obvious to one of ordinary skill in the art. It is further the position of the examiner that the provision of other topical dosage forms, such as creams, in such a kit would also be obvious to one of ordinary skill in the art.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards, Biedermann *et al.*, and Shudo *et al.*

The relevant portions of Petrus, Edwards, and Biedermann *et al.* are detailed in the above rejection of Claims 1-18 under 35 U.S.C. 103(a).

Petrus, Edwards; and Biedermann *et al.* do not provide for kits containing a topical formulation and instructions for use according to a claimed method of treatment.

The Shudo *et al.* publication discloses kits comprising topical patch formulations as well as instructions for use, which may be printed or embodied in the form of electronic media (See Section [0044]). This publication is relied upon primarily as a teaching reference to show that it is known in the art that in certain instances, it may be desirable to provide kits that provide a topical formulation as well as instructions for use in accordance with a disclosed method of treatment.

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. In addition to the arguments presented in the above rejections, the provision of topical dosage forms in a kit that further comprises instructions for use in accordance with the instantly claimed methods of treatment of carpal tunnel syndrome is also considered by the examiner to be obvious to one of ordinary skill in the art. It is further the position of the examiner that the provision of other topical dosage forms, such as creams, in such a kit would also be obvious to one of ordinary skill in the art. Thus, the instantly claimed invention is *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments with respect to Claims 1-23 have been considered but are moot in view of the new grounds of rejection presented above.



*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj0

**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**